K970539

# Summary of Safety and Effectiveness

MAR 24 1997

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. **Submitters Information**

| | |
|---|---|
| Contact person: | William J. Pignato<br>Director of Regulatory Affairs |
| Address: | Chiron Diagnostics Corporation<br>63 North Street<br>Medfield, MA 02052 |
| Phone: | (508) 359-3825 |
| Date Summary Prepared: | February 10, 1997 |

2. **Device Information**

| | |
|---|---|
| Proprietary Name: | Chiron Diagnostics ACS:180 TUp |
| Common Name: | Triiodothyronine uptake test system |
| Device Classification: | Class II, 21 CFR 862.1715 |

3. **Predicate Device Information**

| | |
|---|---|
| Name: | ACS:180 TU Assay |
| Manufacturer: | Chiron Diagnostics Corporation (Formally Ciba Corning Diagnostics Corp.) |
| Document Control # | K925257 |

4. **Device Description**

The thyroid hormones triiodothyronine (T3) and thyroxine (T4) are bound primarily to thyroxine-binding globulin (TBG) and to a lesser extent thyroxine-binding prealbumin (TBPA) and albumin. The ACS:180 T Uptake assay measures the number of unoccupied binding sites on these proteins and is an indirect indicator of thyroid status.

T Uptake (TU) and total T4 are used to estimate the amount of circulating free T4. The estimate, or the Free Thyroxine Index (FTI), is a normalized measurement that remains relatively constant in healthy individuals and compensates for abnormal levels of binding proteins, which can occur in many different physical conditions.

Drugs or physical conditions that alter the patient's TBG levels or drugs that compete with endogenous T4 and T3 for protein-binding sites alter T Uptake results.

When serum contains high levels of T3 or T4, as in hyperthyroidism, fewer unoccupied binding sites are available. Conversely, in hypothyroidism, more binding sites are available.

5. **Statement of Intended Use**

For the assessment of unsaturated thyroid binding proteins in serum or plasma using the Chiron Diagnostics ACS:180® Automated Chemiluminescence Systems.

6. **Summary of Technological Characteristics**

The Chiron Diagnostics ACS:180 TUp assay is a double antibody competitive immunoassay using, chemiluminescent technology. The sample is incubated with Lite Reagent, which is composed of acridinium ester-labeled T3-BGG (bovine gamma globulin) and unlabeled T3. The unlabeled T3 in the Lite Reagent fills available thyroid-binding sites in the sample. The acridinium ester-labeled T3-BGG does not bind to the binding proteins in the sample.

The acridinium ester-labeled T3-BGG and unlabeled T3 compete for monoclonal mouse anti-T3 antibody in the Solid Phase. The monoclonal mouse anti-T3 antibody is bound to goat anti-mouse antibody, which is covalently coupled to paramagnetic particles in the Solid Phase. A greater amount of unlabeled T3 binding to the binding proteins in the sample results in more T3-BGG-acridinium ester binding to the monoclonal antibody, an indication of a higher amount of unsaturated binding proteins.

6. **Performance Characteristics**

**Expected Results**

To confirm the ACS:180 TUp serum reference range, serum samples from 100 apparently healthy individuals were analyzed. Total T4 values were generated on all of these samples using the ACS:180 T4 test method. Based on a 95% confidence interval for euthyroid samples, the following reference range was established:

| Clinical Condition | TU Ratio | % TU | FTI |
|---|---|---|---|
| Euthyroid | 0.75–1.23 | 22.5–37.0 | 1.4–3.1 |

As with all diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

## Performance Characteristics

### *Specificity*

The specificity of the T3 antiserum used in the ACS:180 TUp assay has been determined in the ACS:180 T3 assay.

| Compound | % Cross-reactivity |
|---|---|
| L-thyroxine | <0.1 |
| 3,3',5-triiodothyroacetic acid | ~25 |
| 3,5-diiodothyronine | <0.1 |
| 3,3',5'-triiodothyronine (reverse T3) | 0.6 (by weight) |
| Thyroid hormone analogues | |
| 3-iodo-L-tyrosine | <0.05 (by weight) |
| 3,5-diiodo-L-tyrosine | <0.05 (by weight) |

### *Method Comparison*

For 245 samples with T Uptake ratios in the range of 0.57 to 1.68 (17.1 to 50.4% Uptake) and total T4 values in the range of 3.7 to 14.1 µg/dL (47.73 to 181.89 nmol/L), the correlation between the ACS:180 TUp assay and an alternate chemiluminescent method is 0.95.

The correlation of FTI values (n = 245) is described by the following equation:

ACS:180 TUp FTI = 1.07 (alternate chemiluminescent method) + 0.04

FTI Correlation coefficient (r) = 0.97

### *Precision*

Three samples were assayed 3 times in 6 assays, on each of 4 systems (n = 72 for each sample), over a period of 3 days. Total precision (% CV) ranged from 4.9 to 6.2.